UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: 25-APR-2018

Subject: **Fludioxonil.** Label Amendment to Change Directions for Registered Post Harvest Use to Kiwi.

PC Code: 071503
Decision No.: 535778
Petition No.: NA
Risk Assessment Type: NA
TXR No.: NA
MRID Nos.: 50420101

DP Barcode: D444577
Registration Nos.: 64864-67
Regulatory Action: Amended Use
Case No.: 7017
CAS No.: 131341-86-1
40 CFR: §180.516

From: Sarah Levy, Chemist
Risk Assessment Branch 1 (RAB1)
Health Effects Division (HED; 7509P)

Through: Christine Olinger, Branch Chief
RAB1/HED (7509P)

To: Hope Johnson/Maryam Muhammad (RM21)
Registration Division (RD; 7505P)

Fludioxonil [4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile] is a broad-spectrum contact fungicide and antimicrobial that is active through inhibition of protein kinase leading to reduced growth and development. Fludioxonil is registered for use on a variety of field and vegetable crops, fruit trees, berries, herbs, grasses, ornamentals, residential turf, as a material preservative, for mold remediation and other non-food uses. It can be applied as a seed treatment, an at-planting soil application, and/or broadcast foliar applications. Post-harvest uses are also allowed on selected fruit and root crops.

PROPOSED ACTION

The registrant, Pace International, LLC, has proposed the following changes to the electrofogger FOG-80 FDL label (EPA Reg. No. 64864-67): adding postharvest application to kiwi and changing the currently registered ventilation period. The registrant has proposed the time to turn off the cooling system and humidifiers prior to and during treatment to 2 hours as well as allowing the fog to settle for at least two hours before restarting fans and cooling systems. There is currently a post-harvest use registered for kiwi (water-dispersible granule (WDG) label EPA Reg. No. 100-969). A tolerance is established for residues of fludioxonil, including its metabolites and degradates, in/on kiwifruit, fuzzy at 20 ppm.

The registrant submitted a residue chemistry study which showed the residue levels following a single application via a thermo-fogger (MRID 50420101). Tables 1 and 2 show the supporting residue data for the proposed use on kiwi (MRID 50420101) as well as for the registered use (MRID 46715504).

TABLE 1. Residue Data from Post-harvest Kiwifruit Trial with Fludioxonil (eFOG®-80 FDL); MRID 50420101.

Trial ID (City, State; Year)	Variety	Sample	Treatment type	Total Rate (lb ai)[1]	Commodity	Exposure Time (hours)	Fludioxonil Residues (ppm)
Visalia, CA; 2017	Hayward	QMS.REG.2001-TR1	Post-harvest fumigation	60 mL /metric ton of fruit	Fruit	22	1.31
							1.54
		QMS.REG.2001-TR2			Fruit		1.41
		QMS.REG.2001-TR3			Fruit		1.78
		QMS.REG.2001-TR4					

[1] Electro-fogging (fumigation) was conducted at ambient temperature at a target rate of 60 mL eFOG®-80 FDL/metric ton of fruit in a research fumigation chamber.

TABLE 2. Residue Data from Post-harvest Kiwifruit Trials with Fludioxonil (SC or WP); MRID 46715504.

Trial ID (City, State; Year)	Variety	Formulation	Treatment type (#)	Total Rate (lb ai)[1]	Commodity	PTI[2] (days)	Fludioxonil Residues (ppm)
Visalia, CA; 2004 5310	Hayward	1.9 lb/gal SC	Single dip application (#2)	0.25	Fruit	0	5.1, 4.9
						30	4.5, 4.2
		1.9 lb/gal SC	Single low-volume application (#3)	0.25	Fruit	0	1.4, 2.0
		50% WP	Single dip application (#4)	0.25	Fruit	0	4.2, 0.67
		50% WP	Single dip application (#5)	0.50	Fruit	0	7.5, 6.8
						30	5.4, 8.0
Parlier, CA; 2004 5311	Hayward	1.9 lb/gal SC	Single dip application (#2)	0.25	Fruit	0	2.5, 2.6
						30	3.6, 3.5
		1.9 lb/gal SC	Single low-volume application (#3)	0.25	Fruit	0	2.8, 4.2
		50% WP	Single dip application (#4)	0.25	Fruit	0	3.4, 3.4
		50% WP	Single dip application (#5)	0.50	Fruit	0	6.4, 5.5
						30	3.7, 6.6

[1] Rates are expressed in lb ai/100 gallons for the dip application and in lb ai/200,000 fruit for the low-volume application.
[2] Post-treatment interval; selected samples were refrigerated (7ºC) for 30 days prior to sampling.

Based on a screening-level review, HED notes that the results from the study show that residue levels are below the established tolerance level of 20 ppm for kiwifruit, fuzzy. Adequate storage stability and analytical methodology were submitted.

CONCLUSIONS/RECOMMENDATIONS

As the established tolerance level for kiwifruit, fuzzy, will not be impacted by the submitted residue chemistry data (MRID 50420101), HED has determined that further review of this study is not required. HED concludes that the proposed label amendment is acceptable and the currently-established tolerance of 20 ppm on kiwifruit, fuzzy is adequate to cover the amended use. In addition, a revised human health risk assessment is unnecessary as the most recent dietary (food + drinking water) analysis assumed tolerance-level residues (exposures were less than HED's level of concern; D441215, S. Levy, 20-SEP-2017).

RDI: RAB1 Chemists (18-APR-2018)
S. Levy:S10953:PY-S:(703)305-0783:7509P:RAB1